no. 09/958,057. The Examiner believes that the respective claims are not patentably distinct from each other because all of the co-pending applications claim the use of water-soluble ß-(1,3) glucans as a cosmetic preparation. The Examiner believes that the transition term "comprising" does not exclude any of the additional components claimed by the referenced disclosure. The present application does not describe the use of water-soluble ß-(1,3) glucans as disclosed in the co-pending applications. It does, however, describe the use of a nano-scalar particle produced from the water-soluble ß-(1,3) glucan. In the specification, on pages 2-4, there is described a method for producing a nano-scalar particulate. The claims of the present application are directed to a new and surprising invention, nano-scalar water-soluble products. The nano-scalar water-soluble products have new and surprising effects when compared to a purely water-soluble product as described in the co-pending applications. The particle size creates a different resulting product and therefore not the same or similar product of co-pending applications. Clearly, the double-patenting rejection should be withdrawn because it is divergent.

The claims have been rejected under 35 USC §103(a) as being unpatentable over the Donzis reference, US Patent No. 5,705,184 in view of WO 95 30022, Engstad et al., both of the references cited by Applicants. The Examiner believes the Donzis reference discloses use of insoluble ß-(1,3) glucans with a particle size 1000 nM or less for the revitalization of the skin. The Donzis reference, according to the Examiner, differs from the instant application in that it employs water-insoluble glucans. The Examiner states that the Engstad et al. discloses water-soluble ß-(1,3) glucans having a particle size in the region of 10-300 nM. The Examiner reasons that it would have been obvious to one skilled in the art at the time the invention was made to combine the particles of the Donzis reference with the particles of the Engstad reference in order to incorporate the glucans more easily into cosmetic preparations since they are water-soluble, thereby accelerating the uptake of glucans in topical cosmetic and pharmaceutical preparations.

There appears to be a misunderstanding of the Engstad et al. reference, for it does not describe a water-soluble ß-(1,3) glucan having a particulate nature, but merely describes a water-soluble product, i.e., no particles. In the present application, a method of making a water-soluble nano-scalar particle using the product disclosed in the Engstad et al. reference as a raw material is described in detail and the application relates to the improved qualities this nano-scalar particle possesses as compared to purely non-particulate water-soluble product, as in the Engstad et al. reference, or a water-insoluble product, as in the Donzis reference.

The Donzis reference discloses the use of a particulate water-insoluble glucan that has been subjected to a grinding method resulting in a finer particle size than the more coarse starting material. In the Donzis reference, a method for producing particles to a size of 0.2 microns is claimed, but according to the description at page 2, lines 44-61, the product is passed through an 80 mesh sieve as the only disclosure relating to a method to insure the particle size distribution. An 80 mesh sieve is equal to particle sizes up to 100 microns. The sieved product is then further grinded, but there is no description of how the preferred size of 1 micron or less is separated from the larger sized particles that inevitably will present from such a grinding process, or how large the percentage of the finely ground product containing particles of that specific size is. From the description in the reference Donzis, it is thus impossible to evaluate that the teachings have produced a product containing particles down to 0.2 microns in size. The disclosure does not contain any information or examples where products of different sizes have been compared, and thus showing that a specific particle size has proven efficacy compared to other sizes. In the "Background" area of the reference, it is stated that it is a goal to produce a product that "does not fall out of suspension in dermatological formulations" at page 1, lines 50-54. Thus, there is no indication that the particle size, if accurate, provides any improvement to the efficacy of formulations.

Further, it should be noted that the product described in the Donzis reference is a linear ß-(1,3) glucan, as shown in Fig. 1, whereas the product described in the Engstad et al. reference uses a raw material for making nano-scalar particles as described in the instant application, which is a branched ß-(1,3) glucan.

In view of the foregoing, it is submitted that the Donzis reference, alone or in combination with the teachings of the Engstad et al. reference would not lead one skilled in the art to produce the nano-scalar particulate beta glucan products as claimed in the present application. In this regard, Applicants submit that the claims meet the requirements of 35 USC, and request an early Notice of Allowance.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Christian Kropf et al.

Serial No.: 09/936,747 Group Art Unit: 1616

Filed: September 12, 2001 Examiner: S. Dodson

For: Use of Nanoscalar Water-Soluble B-(1,3) Glucans

THE ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

MARKED VERSION OF AMENDED CLAIMS

1. **[Use of]** **A method of producing cosmetic preparations comprising** nanoscalar water soluble ß-(1,3) glucans, which are substantially free from ß-(1,6) linkages and have particle diameters in the area of 10 to 300 nm, for producing cosmetic and/or pharmaceutical preparations.

2. **[Use]** **The method** according to claim 1, wherein glucans based on yeasts of the family *Saccharomyces* are used.

3. **[Use]** **The method** according to claim 1, wherein glucans are used which have been obtained by contacting glucans with ß-(1,3) and ß-(1,6) linkages in such a way with ß-(1,6) glucanases that practically all ß-(1,6) linkages are loosened, wherafter the lysis products are broght into a nanoscalar form.

4. **[Use]** **The method** according to claim 3, wherein glucans are used which have been treated with glucanases based on *Trichodermia harzianum*.

5. [Us] **The method** according to claim 1, wherein nano particles which are embedded in a protecting colloid are used.

6. [Use] **The method** according to claim 5, wherein polyvinyl alcohol or polyethylene glycol are used as **a** protecting colloid.

7. [Use] **The method** according to claim 1, wherein the glucans are used in amounts of [0,1] **0.1** to 5 % by weight, based on the preparations.

8. [Use] **The method** according to claim 1, wherein the glucans are used for manufacture of hair care agents.

9. [Use] **The method** according to claim 1, wherein the glucans are used for manufacture of skin care and sun protecting agents.